

Office of Research Integrity
Review of Administrative Process
For Responding to Allegations of Scientific Misconduct
Required by 42 CFR Part 50, Subpart A

Institution:

Date:

A review of (name of document), dated, indicated that the following provisions of the Federal regulation noted above are not appropriately reflected in that document. The comment section(s) indicates the needed modification(s).

Applicability

Applies to all individuals who may be involved with a research project supported by the Public Health Service (PHS) or for which an application has been submitted. [§50.101]

Comment:

Definition of scientific misconduct includes the elements of the PHS definition of scientific misconduct. [§50.102]

Comment:

Allegations

Contains explicit procedures for reporting allegations of scientific misconduct to officials within the institution. [§50.103 (a)(1)]

Comment:

Requires immediate response to each allegation of scientific misconduct. [§50.103 (d)(1)]

Comment:

Inquiries

Selection of necessary and appropriate expertise for inquiries. [§50.103 (d)(8)]

Comment:

Prevention of real or apparent conflicts of interest in inquiries. [§50.103 (d)(9)]

Comment:

Affords the affected individual(s) confidential treatment to the maximum extent possible in an inquiry. [§50.103 (d)(2,3)]

Comment:

Notify ORI about immediate health hazards, need to protect Federal funds or equipment and individuals affected by the inquiry, and that the alleged incident will probably be publicly reported. If reasonable indication of possible criminal violations is found, ORI must be notified within 24 hours. [§50.104 (b)(1-5)]

Comment:

Taking appropriate interim administrative actions to protect Federal funds and ensure that the purposes of the Federal financial assistance are being carried out [§50.103 (d)(11)]

Comment:

If an institution plans to terminate an inquiry for any reason without completing all relevant requirements under [50.103 (d)], a report of such planned termination, including a description of the reasons for such termination, shall be made to ORI. [§50.104 (a)(3)]

Comment:

Complete inquiry including report within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. [§50.103 (d)(1)]

Comment:

Documentation of reasons for extending inquiry beyond 60 calendar days. [§50.103 (d)(1)]

Comment:

Content of inquiry report includes evidence reviewed, interview summaries, and conclusions of the inquiry. [§50.103 (d)(1)]

Comment:

Inquiry report given to the respondent(s): comments by respondent made part of the inquiry record [§50.103 (d)(1)]

Comment:

Undertaking diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed [§50.103 (d)(13)]

Comment:

Undertaking diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations of scientific misconduct [§50.103 (d)(13)]

Comment:

Maintain detailed documentation of an inquiry which determines that an investigation is not warranted for at least three years and provide to authorized HHS personnel upon request [§50.103 (d)(6)]

Comment:

Investigations

Selection of necessary and appropriate expertise for investigations. [§50.103 (d)(8)]

Comment:

Prevention of real or apparent conflicts of interest in investigations. [§50.103 (d)(9)]

Comment:

Affords the affected individual(s) confidential treatment to the maximum extent possible in an investigation. [§50.103 (d) (2,3)]

Comment:

Notify ORI about immediate health hazards, need to protect Federal funds or equipment and individuals affected by the investigation, and that the alleged incident will probably be publicly reported. If reasonable indication of possible criminal violations is found, ORI must be notified within 24 hours. [§50.104 (b)(1-5)]

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Taking appropriate interim administrative actions to protect Federal funds and ensure that the purposes of the Federal financial assistance are being carried out [§50.103 (d)(11)]

Comment:

If an institution plans to terminate an investigation for any reason without completing all relevant requirements under [50.103 (d)], a report of such planned termination, including a description of the reasons for such termination, shall be made to ORI. [§50.104 (a)(3)]

Comment:

Promptly advising ORI of any developments during the course of the investigation which disclose facts that may affect current or potential DHHS funding for individual(s) under investigation or that the PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest [§50.103 (d)(12)]

Comment:

Initiate investigation within 30 days of the completion of the inquiry, if findings from that inquiry provide sufficient basis for conducting an investigation [§50.103 (d)(7)]

Comment:

Informing ORI that an investigation will be initiated on or before the date the investigation begins. [§50.104 (a) (1)]

Comment:

Making the report of the investigation available to the respondent(s) for comment: comments made part of the investigation record [§50.104 (a)(2)]

Comment:

Complete investigation and submit report to ORI within 120 calendar days of initiation of investigation. [§50.104 (a)(2)]

Comment:

Submit to the ORI a request for an extension if unable to complete the investigation in 120 days. The extension request should include an explanation for the delay, an interim report on the progress to date, an outline of what remains to be done, and an estimated date of completion. [§50.104 (a)(5)]

Comment:

Final report to ORI must describe the policies and procedures under which the investigation was conducted, how and from whom information was obtained relevant to the investigation, the findings, and the basis for the findings, and include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct, as well as a description of any sanctions taken by the institution [§50.104 (a)(4)]

Comment:

Imposing appropriate sanctions on individuals when the allegation of misconduct has been substantiated [§50.103 (d)(14)]

Comment:

Undertaking diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed [§50.103 (d)(13)]

Comment:

Undertaking diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations of scientific misconduct [§50.103 (d)(13)]

Comment:

Prepare and maintain documentation to substantiate an investigation's findings. This documentation is to be made available to the Director, ORI. [§50.103 (d)(10)]

Comment: